

## **Q. CLINICAL INVESTIGATION FACILITIES**

### **1.0 PURPOSE AND SCOPE**

This section specifies the space planning criteria to be used for Department of Defense (DoD) Clinical Investigation Facilities (CIF). These criteria provide the specialized environment and facilities for the receipt, processing, and housing of laboratory animals used for medical/dental research. In addition, it provides space for staff support, laboratory support, supply/equipment storage, and a surgical area.

### **2.0 DEFINITIONS**

**American Association for Accreditation of Laboratory Animal Care (AAALAC)** This nonprofit organization was formed in 1965 by leading US scientific and educational organizations to promote high quality animal care and use through a voluntary education program. The guidelines by which this organization inspects all facilities is the **Guide for the Care and Use of Laboratory Animals**.

**Animal Research Facility** Any research facility that uses or intends to use live animals in research, tests, experiments, or instructional programs.

**Clinical Investigation** All medical research activities carried out for the purpose of studying either basic science or clinical issues relating to the health and wellbeing of DoD beneficiaries. Most clinical investigation will be carried out in support of graduate medical education programs and supported with designated clinical investigation funds.

**Department of Defense Directive Number 3216.1, 1 Feb 82** "The Use of Animals in DoD Programs." This directive establishes uniform policies, procedures, and responsibilities among DoD components involved in the use of animals. It states that the Clinical Investigative Facility must seek accreditation from the AAALAC.

**Guide for the Care and Use of Laboratory Animals** This is a National Institute of Health Publication by the Department of Health and Human Services which provides additional guidance on housing, caring for, and using laboratory animals.

**Medical Research Facility** Any school (except an elementary secondary school), institution, organization, or person that conducts clinical investigation or other medical research.

**Quarantine** The separation of newly received animals from those already in the facility until the health of the newly received animals has been evaluated.

**The Laboratory Animal Welfare Act of 1966, Subsequent Amendments, and Implementing Regulations** Requires the licensing of dealers, identification of animals, maintenance of records, submission of reports, and compliance with standards for the humane handling, care, treatment, and transportation of animals by dealers and research facilities.

**Vivarium** An enclosed indoor place for keeping and studying terrestrial animals.

### **3.0 POLICIES**

Proper management of animal facilities is essential to the welfare of animals, validity of research data, and health and safety of the animal care staff. Specifically, the animal research laboratory should:

- a. Provide for a caging or housing system that facilitates animal wellbeing, meets research requirements, and minimizes experimental variables. This includes providing space that is adequate, permits freedom of movement, has a resting place, adequate ventilation, meets the biological needs of animals, and provides easy access to food and water.
- b. Meet minimum space recommendations for laboratory animals as outlined in the **Guide for the Care and Use of Laboratory Animals**.
- c. Provide for pens, runs, or other outofcage space for larger species to allow more opportunity for exercise when being held for longer periods of time.

d. Allow for the effective control of the physical environment in terms of humidity, temperature, ventilation, illumination, and noise.

e. Designate areas for bulk storage of food that are

cool, dry, clean, and free of vermin and other potential contaminants. Additionally, bedding should be kept in an area that is off the floor on pallets, racks, or carts.

f. Ensure that animals have continuous access to fresh, potable, uncontaminated drinking water, according to their particular requirements.

g. Establish the use of mechanical equipmentwashing machines. Some means of sterilizing equipment and supplies, such as an autoclave or gas sterilizer, is essential when pathogenic organisms are present or for some specialized facilities or animal colonies.

h. Collect and dispose of waste in a safe and sanitary manner. All 50 states require incineration of all animal bedding and carcass material.

#### **4.0 PROGRAM DATA REQUIRED**

a. Number of Veterinary and Medical Officers assigned	_____
b. Number of Administrative personnel assigned	_____
c. Number of Microbiologists assigned	_____
d. Number of Biochemists and research chemists assigned	_____
e. Number of Histologists assigned	_____
f. Number of Immunologists assigned	_____
g. Number of Hematologists assigned	_____
h. Number of Physiologists assigned	_____
i. Number of Statisticians assigned	_____
j. Number of Nurse Researchers assigned	_____
k. Number of technicians (e.g. laboratory, surgical, veterinary, physiology) assigned	_____
l. Number and Types of animals used	_____
m. Number and types of protocols/year (i.e. active, training)	_____
n. Number of researchers per year not covered above	_____
o. Types of courses held at the Clinical Investigation Facility, frequency, and number of attendees/instructors	_____
p. Type, number, duration, and numberof participants in associated Graduate Medical Education programs	_____

#### **5.0 SPACE CRITERIA**

<b>FUNCTION</b>	<b>NSF AUTHORIZED</b>	<b>PLANNING RANGE /COMMENTS</b>
<b><u>Administration</u></b>		
Office, DirectorCIF	140	140 One per facility.
Secretary	120	Includes computer space and waiting.
Office, Veterinarian	100	One per veterinarian.
Office, Physician	100	One per physician.

Office, Scientist	100	One per scientist.
<b><u>Administration</u></b>		
Office, Admin. Officer	100	If authorized.
Office, Technicians	80	Per technician.
Conference Room/Library	200	Minimum. Additional space requires justification.
Copier/Reproduction	80	One per facility.
Active Files	100	One per facility. Individual study.
Archive Storage	100	One per facility. Individual study.
<b><u>Laboratories</u></b>	*	Justification required for <u>all</u> items
Biochemistry Module	300	*Individual study.
Isotope Room	100	*Individual study.
Microbiology Module	250	*Individual study.
TB/Mycology Module	300	*Individual study.
Tissue Culture Module	300	*Individual study.
Histo/Path Module	220	*Individual study.
Cardiopulmonary Module	300	*Individual study.
Hematology Module	170	*Individual study.
Chemistry Module	280	*Individual study.
Hyperbaric Proced. Room		*Individual study. (size dependent on facility workload)
Nuclear Medicine	500	*Individual study
Grossing Room	150	Grossing Room
Electronmicroscopy	200	*Individual study.
Darkroom	90	*Supports electron microscope. Individual study.
Print Room	100	*Supports electron microscope. Individual study.
Prep Room	100	*Supports electron microscope. Individual study.
<b><u>Laboratory Support</u></b>		
Scintillation Room	100	*Individual study.
Radioactive Waste	80	*Individual study.
Storage	100	*Individual study.
Hazardous Storage	50	*Individual study.
Acid Storage 50	50	*Individual study.
Freezer Rm/Ultra Lo	60	*Individual study.
Refrigerated Storage	200	Refrigerated Storage
Glass Wash/Autoclave	200	*Individual study.
Equipment Storage	150	*Individual study.
<b><u>Staff Support Administration &amp; Laboratory</u></b>		
Toilet, Staff	50	
Staff Lounge	100	Minimum; add 10 NSF per staff member greater than 10. 200 NSF maximum.
Janitor's Closet	40	

**Surgical Area**

Main Operating Room	400	Amount depends on number of protocols. More than one requires individual study. Increase in size requires justification.
Minor Operating Room	200	Amount depends on number of protocols. More than one requires individual study. Increase in size requires justification.
Scrub Alcove	60	Per operating room.
Case Prep Room	150	
Portable XRay Alcove	40	
Recovery Room	100	Individual study.
Central Material Assembly/Processing	150	Individual study.
Decontam/Cleanup	100	
Disposable/Sterile Storage	150	
Small steam sterilizer	60	Per machine. If double door, add 30 NSF.
Medium steam sterilizer	110	Per machine. If double door, add 60 NSF.
Large steam sterilizer	130	Per machine. If double door, add 60 NSF.
Small gas sterilizer/	120	Room includes sterilizer & aerator backup aerator.
Medium gas sterilizer/	200	Add 60, 75, or 100 NSF for aerator each additional small, medium, and large sterilizer/aerator respectively. If double door, add 30, 60, or 90 NSF respectively.
Large gas sterilizer/ aerator	250	
Vet Supply/Pharmacy	100	
Equipment Storage	100	Individual study.

**Staff Support Surgical Area**

Toilet, Female	50	1LAV, 1WC for each 15 women or fraction thereof.
Toilet, Male	60	1LAV, 1WC for each 20 men or fraction thereof.
Janitor's Closet	40	
Shower	30	1 per 20 lockers. Provide one shower for each group of male & female lockers.

**Locker Rooms:**

Male	100	Add 10 NSF per male staff greater than 10.
Female	100	Add 10 NSF per female staff greater than 10.

**Vivarium**

Loading Dock	110	
Animal Receiving	150	
Quarantine Room	250	
Isolation Room	100	
Exam/Treatment Room	150	
Animal Tub Room	80	
Radiography Rad/Fluoro Room	300	Individual study.
Film Processing	120	
View/Film Holding	100	

Xray Control Room	100	
Large Animal Room	175	Number of rooms must be justified according to projected protocols. Individual study.
Small Animal Room	150	Number of rooms must be justified according to projected protocols. Individual study.
Animal Runs (small)	175	Justification required. Individual study.
Animal Runs (Large)	400	Individual study.
Dry Bedding Storage	200	Individual study.
Feed Storage	200	Individual study.
Autoclave	60	Minimum. Individual study.
Equipment/Supply Storage	150	Individual study.
Clean Cage Preparation/ Maintenance	100	
Food Prep/Refrigeration	200	
Cage Storage	600	Individual study.
Cage Washing Dirty	200	
Cage Clean	200	
Cold Room Waste	100	Individual study.
Necropsy	180	
Carcass Refrig Storage	100	
Laundry	100	Individual study.
Clean Linen Storage	50	Individual study.
Dirty Linen Storage	50	Individual study.
Janitor's Closet	40	
<b><u>Staff Support Vivarium</u></b>		
Toilet, Female	60	1LAV, 1WC for each 15 women or fraction thereof.
Toilet, Male	60	1LAV, 1WC for each 20 men or fraction thereof.
Shower	30	1 per 20 lockers. Provide one shower for each group of male & female lockers.
<b>Locker Rooms</b>		
Male	100	Minimum. Add 10 NSF per male staff greater than 10.
Female	100	Minimum. Add 10 NSF per female staff greater than 10.
Lounge	100	